REMARKS

The above-identified Application has been carefully reviewed with the Office Action of July 9, 2008, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicant submits the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

It is noted that the Restriction Requirement mailed on 18 April 2008 has been withdrawn and that claims 17-36 will be examined. The Applicant appreciates withdrawal of the Restriction Requirement and the Examination of all the claims.

Claims 20 and 36 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 20, claim 20 is amended herein. This amendment is believed to remove any indefiniteness for the claim and support for the amendment is found in the Applicant's Specification on Page 11, lines 20-23. Favorable reconsideration is hereby respectfully requested.

Regarding claim 36, the Office takes the position that the recitation "sufficient for protecting the balloon against gamma radiation" renders the claim vague and indefinite since undue experimentation is required to determine the concentrations sufficiency.

The Applicant respectfully traverses this rejection as the recitation in the claim "sufficient for protecting the balloon against gamma radiation" is merely a limitation which does not require "undue experimentation". Actually, a skilled person, using the conventional method of trial and error, would have absolutely no difficulty to arrive at the method as claimed. Favorable reconsideration with regard to claim 36 is also hereby respectfully requested.

Claims 17-18, 20-23, 27-29, 32, 33, 35, and 36 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Kuyava (U.S. Patent No. 6,558,315), the Office taking the position that regarding claim 17, Kuyava discloses a penile prosthesis or "intragastric balloon" including an expandable and inflatable cylinder or "flexible bag" (18) having inside and outside surfaced coated with parylene (Col. 5, lines 1-5, Fig. 1), and that regarding claims 17-26 it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham 2 USPQ2d 1647 (1987).

A proper rejection of a claim under 35 U.S.C. § 102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock,*

Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990).

It is the Applicant's position that Kuyava does not anticipate the subject matter of the claims, because Kuyava discloses a penile prosthesis, namely, a prosthesis suitable for being implanted in the penis. The presently claimed device relates to an intragastric balloon, namely a balloon suitable for being implanted in the stomach. The Ex parte Masham case is inapposite in this case as the Kuyava apparatus does not teach all of the structural limitations of independent claims 1 and 27, or the method claim 32 (which is admitted later in the Office Action in Paragraph 13). Claim 1 recites, "at least a portion of said surface is covered by a coating comprising parylene". Claim 27 recites, "depositing a coating of parylene on at least a portion of a surface..."

Kuyava teaches coating a substantial portion of the inside and outside surfaces with parylene (Col. 5, lines 1-3). Given the use to which the Kuyava device is put, it needs to be resistant to frequent expansion and contraction which leads to bending and thus the frictional wear and tear which Kuyava is trying to avoid. A penile prosthesis is further not suitable for being implanted in the stomach, if only because of its elongated shape which would allow the prosthesis to go to the intestine, which would be extremely dangerous for the patient.

Furthermore, the intragastric balloon of the invention is intended for treating obesity. This means that the size of the balloon is sufficient for generating a sensation of being sated, as explained in the Specification. The penile prosthesis is too small to have any significant effect for treating obesity if it was implanted in the stomach.

Claims 17, 27, and 32 are the independent claims. As it is submitted that Kuyava does not anticipate these independent claims, and these independent claims are believed to be in condition for allowance, it is submitted that the dependent claims are also in condition for allowance and the rejection should be withdrawn.

Claim 19 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuyava in view of Yan (U.S. Patent No. 6,287,277).

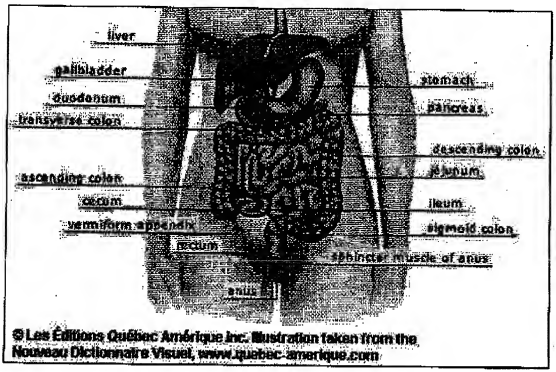
As claim 19 is dependent on allowable claim 17, it is believed to be in condition for allowance.

Claims 17, 18, 20-26, and 31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Moll (U.S. Patent No. 5,361,752) in view of Kuyava, the Office taking the position that Moll et al discloses at least one expandable and inflatable cylinder or "flexible bag"

(5) having inside and outside surfaces (Fig. 1) but that Moll fails to disclose a flexible bag coated with parylene. The Office Action continues using Kuyava to supply a teaching of a penile prosthesis coated with parylene. The Office then concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the flexible bag of Moll et al with the parylene coating as taught by Kuyava for the predictable result of providing the flexible bag with a frictionless, wear-resistant, and leak proof exterior to eliminate ruptures that are occur with frequent inflation and deflation.

For a proper rejection of a claim under 35 U.S.C. §103, the cited combination of references must disclose, teach, or suggest all elements/features of the claim at issue. *See, e.g., In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988) and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981) (emphasis added).

This rejection is believed to be in error and should be withdrawn. Moll does not disclose an intragastric balloon for treating obesity. The device disclosed by Moll is a retraction device which is not suitable for being implanted in the stomach, if only because of its important size which clearly exceeds the size of the stomach. A drawing figure is included herewith to illustrate. The stomach is smaller than the liver as shown in the figure provided herewith. The device of Moll is intended to be implanted in the abdomen. Therefore, a skilled person would never insert the retractor of Moll in the stomach, since inflation of said retractor would lead to explosion of the stomach.



In addition, the combination of Kuyava and Moll does not in any sense disclose an intragastric balloon for treating obesity and even if the references are combined, it is impossible to arrive at the claimed device. The deficiencies of the Kuyava teaching are repeated here as well as the distinction in the surface coating. While the dependent claims are discussed in some detail, as they are dependent on allowable independent claims 17 and 27, it is believed that the dependent claims are also in condition for allowance.

Claims 30 and 34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuyava in view of Lafont et al (U.S. Patent No. 5,957,975), the Office taking the position that Kuyava fails to disclose the method step of sterilizing the balloon through the use of gamma radiation but that Lafont et al teach a system including a stent, catheter, and balloon that are sterilized by the standard procedure of gamma radiation and therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have sterilized the balloon of Kuyava using gamma radiation as taught by Lafont et al, because it was a standard procedure to purify medical devices before their introduction into the body.

This rationale is both incomplete and improper in view of the established standards for rejections under 35 U.S.C. § 103.

In this regard, the MPEP section 2141 states:

> The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966))... As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:
>
> (A) Ascertaining the differences between the claimed invention and the prior art; and
>
> (B) Ascertaining the differences between the claimed invention and the prior art; and
>
> (C) Resolving the level of ordinary skill in the pertinent art.

In addition:

> When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:
>
> (A) The claimed invention must be considered as a whole;
>
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
>
> (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
>
> (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As reflected above, the foregoing approach to obviousness determinations was recently confirmed by the United Stated Supreme Court decision in KSR INTERNATIONAL CO. V. TELEFLEX INC. ET AL. 550 U.S. 1, 82 USPQ2d 1385, 1395-97 (2007), where the Court stated:

> In Graham v. John Deere Co. of Kansas City, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in Hotchkiss v. Greenwood, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:
>
> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Id., at 17–18.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" (MPEP 2141). Simply stated, the Office Action has failed to at least (1) ascertain the differences between and prior art and the claims in issue; and (2) resolve the level of ordinary skill in the art. Furthermore, the alleged rationale for combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale.

This rejection is believed to be in error and should be withdrawn. Using gamma radiation to sterilize a medical device may adversely influence the future properties of the device material, especially if the material is an elastomer. This is why, although using gamma radiation for sterilization is indeed a standard procedure, it cannot be used on any medical device, since some of them, because of the nature of their constituting material, may be damaged. A skilled person, taking into account that Kuyava's prosthesis is made of silicone, would have been deterred from using gamma radiation since it is well known in the art that gamma radiation may damage silicone.

Claims 17, 20, 23, 27, 28, and 31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Weiner et al (U.S. Patent No. 4,694,827) in view of Goldsteen et al (U.S.

Patent No. 5,976,178). Here the Office takes the position that regarding claim 17 and the method of claim 31, Weiner et al disclose a flexible balloon that is insertable within the stomach and has inside and outside surfaces but fails to disclose a coating of parylene. The Office then uses the Goldsteen reference to teach the application of coatings to obtain biocompatibility and a high degree of smoothness which includes parylene. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to have provided the balloon of Weiner et al with a parylene coating as taught by Goldsteen et al.

While it is true that Weiner et al disclose an intragastric balloon for treating obesity, for the reasons propounded in the previous response (and which had convinced the Office to abandon the objection for lack of unity), the approach of the Office for this point for assessing an inventive step is clearly an *ex post facto* analysis, and that an objective approach leads to a completely different conclusion, namely that the presently claimed device and method do not lack an inventive step. As noted previously in the Response filed 19 May 2008, the Goldsteen et al reference relates to an implant (graft) that has nothing in common with an intragastric balloon. The graft is of a very small size (while an intragastric balloon is bulky) and the graft is preferably made porous, while an intragastric balloon should not be porous to avoid any fluid leakage.

There is nothing in the Goldsteen et al. patent that allows the skilled person to establish a link between the goals to be reached (decreasing porosity and facilitating folding and deployment) and the parylene. Indeed, the word parylene is mentioned only at Col. 19, line 47 of the Goldsteen et al patent, among a long list of possible coatings, and no specific information is given about its properties, except that it is commonly used to coat pacemakers, which is irrelevant for the skilled person wanting to improve an intragastric balloon. The Office has identified the Goldsteen et al patent because it was searching for implants coated with parylene, thereby clearly using foreknowledge of the invention. Such hindsight reconstruction is clearly inappropriate and it is believed that this rejection can now be withdrawn.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the under undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,

James W. Kayden, Reg. No.: 31,532

THOMAS, KAYDEN,
HORSTEMEYER & RISLEY, L.L.P.
Suite 1500
600 Galleria Parkway N.W.
Atlanta, Georgia 30339
(770) 933-9500